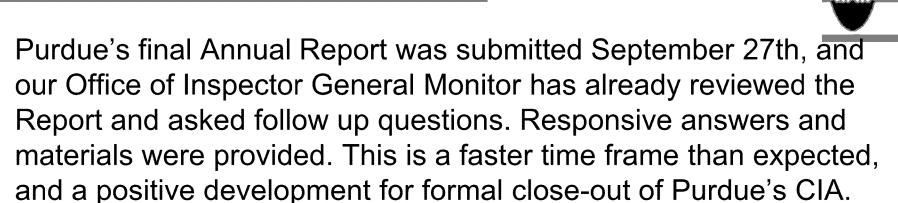
## Exhibit 46

# 4Q2012 Compliance Report to the Board of Directors

# Bert Weinstein Vice President, Corporate Compliance January 2013



#### **Corporate Integrity Agreement**



Subsequent to submission of the Final Report, Compliance discovered an Intermezzo Sales Force District Manager was not performing job responsibilities during the term of the CIA with respect to Ride-Alongs, among other things – a CIA requirement (DM terminated). Decision was reached to report to this to OIG, and extensive information was provided to OIG about our investigation and remedial actions (a copy of our letter to the OIG is available upon request). We do not expect adverse impact to the close-out of the CIA from this matter.



#### **Compliance Environment Hostile**



- The US Department of Justice, FDA, OIG, and state enforcement agencies continue to focus on the pharmaceutical and device industries
- \$6 billion in pharma settlements in 2012 alone (GSK \$3 billion, Abbott \$1.5 billion), compared to ~\$15 billion during 2000-2011
- Five of the 2012 matters included criminal components to the settlements, mainly for off-label promotion of products
- Punishment of individuals is now the focus, with exclusion and incarceration more likely



#### New (2012) CIA Requirements



New CIAs focus on particular company issues, but reflect OIG's wider views on what makes for an effective compliance program. OIG's views of the industry have become more sophisticated and nuanced. The most recent CIAs contain the following new elements:

- Sales Representative Incentive compensation plans must minimize risk of off-label promotion and exclude compensation for off-label prescribing/promotion; there are "claw-back" provisions for executive incentive compensation
- Transparency/disclosure requirements are increasing --Disclosures of interest required of Consultants and authors; reporting of physician payments, medical education grants, charitable contributions, clinical trials, post marketing commitments and other transfers of value to HCPs/customers, more broadly than will be required under Sunshine Act



#### New (2012) CIA Requirements



- Semi-annual product-by-product risk management plans
- Monitoring requirements continue to expand to include more promotional, non-promotional, and managed care functions:
  - Sales Representative call notes, documents, emails, promotional materials
  - Consulting arrangements, speaker programs, publication activities, medical education grants, research studies
  - Medical Services materials
  - Medical personnel interactions with HCPs
- Annual reviews of call plans and sample plans
- Pricing and rebate reviews

Purdue's Compliance department considers and adopts new OIG requirements to our compliance program, where applicable



#### **Sunshine Act Update**



Implementation of Federal Physician Payments Sunshine Act has been delayed by lack of final regulations by HHS.

- HHS Administrator testified to Senate Committee in September - "hope" some data would begin to be captured for 2013
- With many unanswered questions as to formatting of data, treatment of clinical trial related expenses, coverage of certain ownership interests
- Industry is seeking180 days to implement final regulations when issued



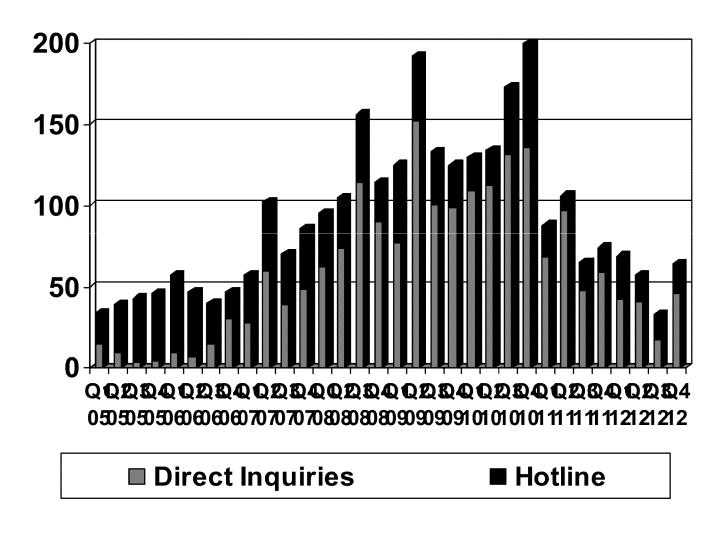
#### **Overall Compliance Performance**

- Throughout 4Q12, the Company continued to maintain a state of effective compliance, with all components of the Annual Compliance Scorecard above the established standards, including Sales and Marketing, Manufacturing and Quality, and R&D
- While there are numerous compliance matters detected, investigated, and remediated on an on-going basis, there have been no significant compliance matters to report for 4Q12, with the exception of the Intermezzo District Manager non-performance matter discussed above.
- The following slides display 4Q12 compliance matters (64 total), and 2012 full year matters (279 total, 1/1/12-12/3/12).



#### Matters by Quarter (1Q05 – 4Q12)

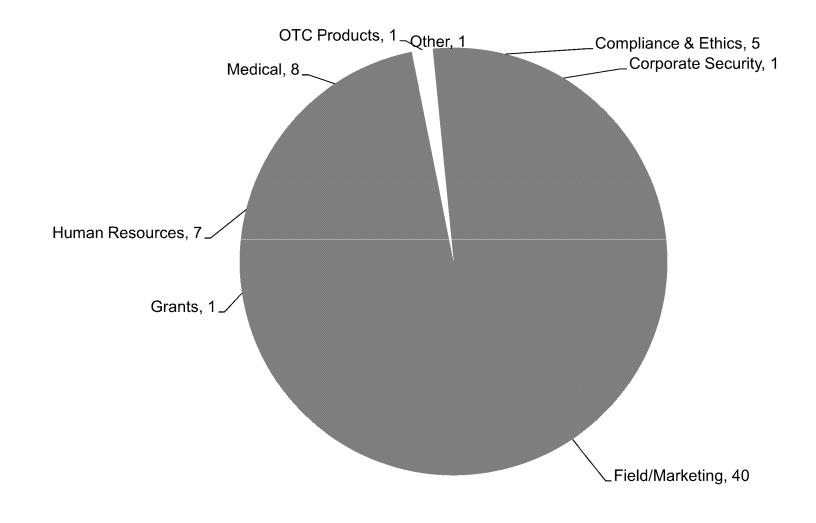


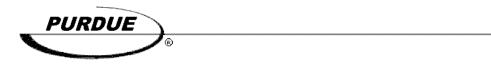




#### **4Q 2012 Compliance Matters**







### **Full Year 2012 Compliance Matters**



